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Agenda Radiological Devices Panel Meeting

March 5, 2001

Purpose of the Meeting - To discuss, make recommendations and vote on a premarket approval application (PMA P000041) for a computer-aided detection (CAD) device for identifying regions of interest in chest radiographs.

9:00 - 9:15 Call to order and the Chair's Introduction – Brian S. Garra, M.D.
Update on FDA Radiology Activities - Robert A. Phillips, Ph.D.
FDA Introductory Remarks - Robert J. Doyle, Executive Secretary

Open Public Hearing

9:15 – 9:45 Open Public Hearing

Open Committee Discussion

9:45 - 10:00 ROC Overview - Robert F. Wagner, Ph.D.

10:00 - 10:05 Charge to the Panel - Brian S. Garra, M.D.

10:05 - 11:30 Presentations on P000041 by sponsor

- Introduction - Michael H.Y. Yeh, Ph.D.
- Lung Cancer - Charles White, M.D.
- CAD in Chest Radiography - Kunio Doi, Ph.D.
- RapidScreen RS-2000 System - Ed Martello
- Case Examples and Clinical Trial - Ron Khazan, M.D.
- Clinical Study Results and Conclusions - Matthew Freedman, M.D., M.B.A.

11:30 - 12:15 Presentations on P000041 by FDA

- PMA Overview - Robert Doyle
- Clinical Review - William Sacks, Ph.D., M.D.
- Statistical Analysis - Marina Kondratovich, Ph.D.

March 2, 2001

- Summary Conclusions - William Sacks, Ph.D., M.D.

12:15 - 1:00 Lunch

Open Committee Discussion

1:00 - 3:00 Panel Discussion - Alicia Y. Toledano, Sc.D., Lead Discussant

3:00 - 3:15 Break

Open Public Hearing

3:15 - 3:45 Open Public Hearing

Open Committee Deliberations

3:45 – 4:30 Panel Recommendation(s) and vote

4:30 Adjourn

March 2, 2001

TRAINING

7:30 - 9:00 Training for new SGE's 110X

March 2, 2001